

STABILIZED PEROXIDE GELS CONTAINING FLUORIDE

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to dental products for promoting health in the oral cavity.

2. The Related Art

Oral compositions containing both a peroxide and sodium bicarbonate have been acclaimed by the dental profession, especially through the work of Keyes. See Keyes et al. "Periodontics and Oral Hygiene", January 1978, pages 51-56. Formulations based on the Keyes technology, especially the peroxide component, are particularly prone to decomposition. The literature has reported considerable research directed at the stability problem. For instance, see U.S. Pat. Nos. 3,577,521 (Scheller), 4,837,008 (Rudy et al), 4,130,501 (Lutz), 4,895,721 (Drucker) and 4,343,785 (Schmolka). A quite successful approach to the problem has involved physical segregation of the peroxide into a compartment separate from co-reactive ingredients. U.S. Pat. Nos. 4,849,213, 4,687,663 and 4,528,180, all to Schaeffer, disclose a package with a dual-compartment respectively storing a peroxide gel and a bicarbonate paste.

Related technology is described in U.S. Pat. No. 4,487,757 (Kiozpeoplou) which describes a toothpaste in a dispenser that physically separates sodium bicarbonate from acidic ingredients, e.g. citric or ascorbic acids, to prevent contact therebetween prior to usage.

In U.S. Pat. Nos. 4,788,052, 4,839,156 and 4,839,157 (all to Ng et al) are described aqueous hydrogen peroxide gel dentifrices that can be stabilized by use of a combination of hydrophilic and hydrophobic fumed silica. Aqueous mouthrinses have been described in U.S. Pat. No. 5,104,644 (Douglas) that contain hydrogen peroxide. Also present at relatively low concentrations are such additives as zinc chloride, surfactant, sodium citrate and citric acid. It should be noted that neither the Ng et al nor Douglas patents include fluoride anions within the suggested compositions.

From the aforementioned art, it becomes apparent that hydrogen peroxide compositions should be formulated as simply as possible to minimize potential interactions between the peroxide and the remaining ingredients.

Fluoride anion is known by those skilled in the art as a destabilizing factor in peroxide gels. The desirability of achieving anticaries protection for oral products has prompted formulators to seek a satisfactory means to allow fluoride incorporation. In U.S. Pat. Nos. 5,037,633 and 5,037,634 to Williams et al. and Ziemkiewicz et al., respectively, the problem was solved by incorporating sodium fluoride into a bicarbonate paste intended to be co-extruded with a peroxide gel, each from a separate compartment of a dual-compartment container. See also U.S. Pat. No. 5,059,417 (Williams et al.) detailing the peroxide technology.

While relegating fluoride to the bicarbonate component may solve the anticaries problem, there still remains the problem of dispensing a constant volume of both peroxide gel and bicarbonate paste; accurate dosage of fluoride based on total dentifrice volume is thereby ensured. Only with a special, costly pump is such precise delivery achievable.

Consequently, a system has been sought which permits both the bicarbonate and the peroxide components

to each incorporate an identical fluoride anticaries agent thereby eliminating need for a costly pump.

Beyond stabilization, any new anticaries system must have consumer satisfactory taste and have no disruptive influence upon rheology, product color or other physical parameters.

Recently it has been reported in U.S. Pat. No. 5,217,710 (Williams et al) that tin compounds, especially stannous ion, may stabilize hydrogen peroxide in the presence of a fluoride compound. Unfortunately, there are two problems with this technology. The first is that stannous ions impart an unsatisfactory metallic taste to the otherwise fine organoleptic properties of the dental compositions. Secondly, the tin compounds have caused severe corrosive pitting of stainless steel reactors in which the dental products were manufactured.

Accordingly, it is an object of the present invention to provide a peroxide-containing composition capable of use with a bicarbonate composition wherein both compositions contain a fluoride anticaries agent and there is no adverse effect upon product stability.

A further object of the present invention is to provide a peroxide composition and a bicarbonate composition held in separate compartments of a dual-compartment delivery system wherein each of the compositions contains an identical fluoride anticaries agent.

A still further object of the present invention is to provide a peroxide composition that incorporates a fluoride anticaries agent such that the composition has consumer-acceptable taste and maintains color, e.g. blue.

A still further object of the present invention is to provide a peroxide gel composition including a fluoride anticaries agent and a stabilizing system that inhibits peroxide decomposition while still maintaining a clear gel.

A still further object of the present invention is to provide a peroxide composition that incorporates a fluoride anticaries agent and a stabilizing system that has no adverse corrosive effect upon stainless steel manufacturing vessels.

Another object of the present invention is to provide a method for inhibiting caries and also promoting gum health through application of a peroxide and a bicarbonate composition, each containing a fluoride compound and each delivered simultaneously from separate compartments of a dual-compartment dispenser.

These and other objects of the present invention will become more readily apparent upon consideration of the more detailed description and Examples which follow.

SUMMARY OF THE INVENTION

An oral composition is provided comprising:

- (i) from about 0.1 to about 10% by weight of a peroxide compound;
- (ii) a physiologically-acceptable fluoride-containing compound present in an effective amount to inhibit formation of caries on teeth; and
- (iii) a zinc compound present in an effective amount to stabilize the peroxygen compound against decomposition by the fluoride-containing compound.

A method is also provided for stabilizing peroxygen compounds against decomposition, the method including applying to the teeth a composition comprising:

- (i) from about 0.1 to about 10% by weight of a peroxide compound;